

ABBOTT LABORATORIES
Form 8-K
October 14, 2005

SECURITIES AND EXCHANGE COMMISSION

Washington, D. C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

October 13, 2005

Date of Report (Date of earliest event reported)

ABBOTT LABORATORIES

(Exact name of registrant as specified in its charter)

Illinois
(State or other Jurisdiction
of Incorporation)

1-2189
(Commission File Number)

36-0698440
(IRS Employer
Identification No.)

100 Abbott Park Road
Abbott Park, Illinois 60064-6400

(Address of principal executive offices)(Zip Code)

Registrant's telephone number, including area code: **(847) 937-6100**

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 7.01 Regulation FD Disclosure

Abbott Receives Not-Approvable Letter From FDA for New Drug Application on Xinlay (atrasentan)

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On October 13, 2005, Abbott received a not-approvable letter from the U.S. Food and Drug Administration (FDA) for the New Drug Application (NDA) regarding the oral investigational agent Xinlay (atrasentan) for use in patients with metastatic hormone-refractory prostate cancer (HRPC). This decision does not affect the ongoing trial M00-244, which is evaluating Xinlay in patients with non-metastatic HRPC. The FDA's Oncologic Drugs Advisory Committee (ODAC) did not recommend approval in September.

Private Securities Litigation Reform Act of 1995 A Caution Concerning Forward-Looking Statements

Some statements in this news release may be forward-looking statements for the purposes of the Private Securities Litigation Reform Act of 1995. We caution that these forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those indicated. Economic, competitive, governmental, technological and other factors that may affect Abbott's operations are discussed in Exhibit 99.1 of our Securities and Exchange Commission Form 10-Q for the period that ended March 31, 2005, and are incorporated by reference. We undertake no obligation to release publicly any revisions to forward-looking statements as the result of subsequent events or developments.

This Report is Being Furnished

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The information in Item 7.01 of this report is being furnished, not filed, pursuant to Regulation FD. Accordingly, the information in Item 7.01 of this report will not be incorporated by reference into any registration statement filed by Abbott under the Securities Act of 1933, as amended, unless specifically identified therein as being incorporated therein by reference. The furnishing of the information in this report is not intended to, and does not, constitute a determination or admission by Abbott, that the information in this report is material or complete, or that investors should consider this information before making an investment decision with respect to any security of Abbott.

SIGNATURE

SIGNATURE

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Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ABBOTT LABORATORIES

Date: October 14, 2005

By: /s/ Thomas C. Freyman
Thomas C. Freyman
Executive Vice President,
Finance and Chief Financial
Officer